

SECTION 11

REGULATORY OPTIONS SELECTION

11.1 Introduction

This presents the final selected regulatory options for the pharmaceutical manufacturing industry and discusses the factors considered in determining the selected options for BPT, BAT, NSPS, PSES, and PSNS. Factors considered included: reduction in pollutant discharges to the environment, costs to the industry, age of the equipment and facilities involved, the manufacturing processes used, process changes required, nonwater quality environmental impacts, engineering aspects of the control technologies, and energy requirements.

The regulatory options selected provide the technology basis of the effluent limitations guidelines and standards presented in Sections 13 (BPT), 15 (BAT), 16 (NSPS), and 17 (PSES and PSNS). Selection of the BCT option is determined by the BCT cost test analysis, which is discussed in 14. Owners or operators of facilities subject to these regulations would not be required to use the specific wastewater treatment technologies selected by EPA to establish the limitations and standards. Rather, a facility could choose to use any combination of process changes, water use changes, and wastewater treatment to comply with the limitations and standards provided that the limitations and standards are not achieved through prohibited dilution.

Sections 11.2 through 11.6 provide an overview of the regulatory options considered, the options selected as the bases of the final regulation, and the rationale for options selected under BPT, BAT, NSPS, PSES, and PSNS, respectively.

11.2 BPT

Effluent limitations guidelines based on the best practicable control technology currently available apply to direct discharges and are generally based on the average of the best existing performance, in terms of treated effluent discharged by facilities in a subcategory. BPT focuses on end-of-pipe

treatment technology and such process changes and internal controls that are common industry practice. Based on 304(b)(1)(B) of the CWA, the factors considered in assessing BPT include:

- The cost of achieving effluent reductions in relation to the effluent reduction benefits;
- The age of equipment and facilities involved;
- The process used;
- Process changes required;
- Engineering aspects of the control technologies;
- Nonwater quality environmental impacts (including energy requirements); and
- Other factors the Administrator deems appropriate.

The Agency is not changing the current BPT effluent limitations set for pH in the November 17, 1976 interim final regulation for the pharmaceutical manufacturing industry.

Table 11-1 lists the BPT regulatory options considered by the Agency as discussed in 7.3.2.

EPA has determined to revise BPT effluent limitations only for COD for Subcategories A, B, C, and D. EPA is also clarifying the compliance monitoring requirements for the existing BPT limitations for cyanide for Subcategories A and C, and withdrawing the existing cyanide limitations for Subcategories B and D. By revising BPT (and BAT) for COD, plants will not only remove large amounts of COD, but also achieve significant incidental removals of BOD₅ and TSS. For this reason, EPA has determined that it is not necessary to separately revise the BPT limits for BOD₅ and TSS in this case.

EPA has determined to revise BPT for COD because the biological treatment technology used as a basis for the limitations really represents BPT technology and is widely used in the industry. 31

of 38 direct discharging pharmaceutical manufacturing facilities currently use on-site activated sludge biological treatment as part of their wastewater treatment systems.

The bulk parameter and nonconventional pollutant COD is an indicator of organic matter in the wastestream that is susceptible to strong oxidation, and as such would also contain much of the BOD₅ that would be measured. In addition, limited studies and discharge monitoring data have identified toxicity associated with the COD levels contained in effluents from pharmaceutical manufacturing facilities.

With regard to cyanide, EPA is retaining the existing BPT limitations for the A and C subcategories. EPA did not revise the BPT cyanide limitations because the removal achievable by the limitations was estimated to be less than 38 pounds per year and was deemed to be not significant in relation to the annualized costs.

However, EPA is modifying the requirements for compliance monitoring (for Subcategories A and C). The current limitations require compliance monitoring after cyanide treatment and before dilution with other wastestreams, or in the alternative, monitoring after mixing with other wastestreams based on a standard dilution factor. The modified monitoring requirements do not change the prohibition on dilution to meet the effluent limitations for cyanide. Monitoring for compliance with the existing limitations is required in-plant, prior to the commingling of cyanide-bearing wastestreams with non-cyanide-bearing wastestreams for those facilities where the cyanide levels would be below the level of detection at the end-of-pipe monitoring location. The only change in the monitoring requirements is to eliminate the current dilution standard that applied industry-wide, and to allow individual facilities to demonstrate that end-of-pipe monitoring for cyanide is feasible (*i.e.*, cyanide is detectable once dilution effects are accounted for); those facilities may continue to monitor at the end-of-pipe. EPA is withdrawing the cyanide limitations for Subcategories B and D, as cyanide is not used or generated in these subcategories.

11.3 BAT

Effluent limitations guidelines based on the best available technology economically achievable represent the best existing economically achievable performance of plants in the industrial subcategory. The CWA establishes BAT as the principal national means of controlling the direct discharge of priority pollutants and nonconventional pollutants to waters of the United States. Based on 304(b)(2)(B) of the CWA, the factors considered in assessing BAT include:

- The age of equipment and facilities involved;
- The process used;
- Process changes required;
- Engineering aspects of control technologies;
- The cost of achieving effluent reduction;
- Nonwater quality environmental impacts (including energy requirements);
and
- Other factors the Administrator deems appropriate.

The Agency retains considerable discretion in assigning the weight to be accorded these factors. BAT may include process changes or internal controls, even when these technologies are not common industry practice.

Table 11-1 lists the BAT regulatory options considered by the Agency as discussed in 7.3.4. Analysis of the impacts of these options in terms of reduction in pollutant discharges to the environment, costs to industry, and nonwater quality environmental impacts (including energy impacts) are described in 9, 10, and 12, respectively.

For Subcategories A and C, EPA evaluated the costs and economic impacts associated with each option and determined that all the options were economically achievable. After considering the pollutant load removals, the costs, as well as the non-water quality environmental impacts

associated with the options, EPA selected the third option which adds effluent limitations for 30 organic pollutants, ammonia and COD and clarifies the cyanide monitoring requirements. EPA believes that this option is economically achievable and there are no significant adverse non-water quality impacts associated with it. In addition, EPA believes the discharge loadings of ammonia, COD and the organic pollutants are significant from Subcategory A and C facilities, and that limitations on these discharges are appropriate. EPA has also evaluated the technology bases of the final BAT limitations in the context of the BAT statutory factors, *i.e.*, the age of equipment and facilities involved, the process(es) employed, potential process changes and non-water quality impacts such as energy requirements. EPA believes the final BAT limitations are appropriate based on its assessment of these factors in relation to A and C subcategory facilities.

For Subcategories B and D, EPA has identified only the pollutant COD for control by BAT limitations based on advanced biological treatment (the technology selected as the basis for the BPT limitations). As discussed under BPT, cyanide is not a pollutant of concern for Subcategory B and D operations and EPA is withdrawing the current BAT cyanide limitations for facilities with subcategories B and D operations. EPA also has determined that ammonia is not a pollutant of concern for these subcategories since ammonia is not found in significant amounts in wastewaters from these operations.

EPA has evaluated the discharge loadings of organic pollutants from Subcategory B and D facilities and has determined that 95 percent of the discharge of organic pollutants is from two facilities. Most direct discharging Subcategory B and D facilities do not discharge any organic pollutants. EPA believes these organic pollutant discharges are not sufficient to justify national regulations for these subcategories. If permit writers determine the need to further control the organic pollutants from the two facilities, the appropriate limits contained in the Subcategory A and C BAT regulations may be used. EPA has selected the first option, which is to only add the BPT revised COD limitations to BAT for Subcategory B and D facilities, and to withdraw the existing cyanide limitations.

11.4 NSPS

The basis for new source performance standards under 306 of the CWA is the best available demonstrated technology. Industry has the opportunity to design and install the best and most efficient pharmaceutical manufacturing processes and wastewater treatment systems at new plants. Accordingly, Congress directed EPA to consider the best demonstrated alternative processes, process changes, in-plant control measures, and end-of-pipe wastewater treatment technologies that reduce pollution to the maximum extent feasible. In response to that directive, and as with the development of options for the BAT effluent limitations guidelines, EPA considered effluent reductions attainable by the most advanced and demonstrated process and treatment technologies at pharmaceutical manufacturing facilities.

The general approach followed by the Agency for developing NSPS options was, where appropriate, to evaluate the best demonstrated processes for control of priority and nonconventional pollutants at the process level and best demonstrated end-of-pipe treatment for control of conventional pollutants and additional control of certain nonconventional pollutants. The factors considered in assessing NSPS include:

- The demonstration status of the process and wastewater treatment technologies;
- The cost of achieving effluent reductions;
- Nonwater quality environmental impacts; and
- Energy requirements.

For Subcategories A, B, C, and D, EPA evaluated technology options capable of achieving greater pollutant removal of conventional pollutants (BOD₅ and TSS), COD, organics, cyanide and ammonia than the selected bases for existing source limitations (BPT, BCT, and BAT). The only option potentially capable of achieving additional removals involves the use of granular activated carbon (GAC) adsorption technology. This technology is capable of reducing the COD

from some direct discharging A and C subcategory facilities. However, there is only limited GAC performance data available, from one pilot study.

Therefore, EPA is promulgating NSPS equal to the final BAT effluent limitations for organic pollutants, cyanide, and ammonia. EPA is also promulgating revised NSPS for BOD₅, COD and TSS for all four subcategories at a level equal to the discharge characteristics of the best performing BPT plants. For COD this is equivalent to the BAT/BPT level of control. These final standards are based on the best available demonstrated control technologies, which include advanced biological treatment for all four subcategories, and cyanide destruction and nitrification for Subcategories A and C. In developing these final standards, the Agency considered factors including the cost of achieving effluent reductions, non-water quality environmental impacts, and energy requirements. EPA finds that the final standards represent the best available demonstrated control technologies, are economically achievable and have acceptable non-water quality environmental impacts.

11.5 PSES

Pretreatment standards for existing sources are designed to prevent the discharge of pollutants which pass through, interfere with, or are otherwise incompatible with the operation of POTWs. The CWA requires pretreatment for pollutants that interfere with or pass through POTWs in amounts that would exceed direct discharge effluent limitations or limit POTW sludge management alternatives, including the beneficial use of sludges on agricultural lands. The Agency is also requiring pretreatment for pollutants that pass through POTWs due to the pollutant exhibiting significant volatilization prior to treatment by a POTW. The transfer of a pollutant to another media (air) through volatilization does not constitute treatment. PSES are to be technology-based and analogous to BAT for removal of priority and nonconventional pollutants.

Table 11-1 lists the PSES regulatory options considered by the Agency as discussed in 7.3.6.

For Subcategory A and C facilities, due to the low pollutant removals achievable by the revised cyanide standards (approximately 1,000 lbs. Per year with 97 percent of the removals coming from one facility) in relation to the compliance costs, EPA has decided not to revise the existing cyanide standards, and has selected the option to add organics and ammonia only and modify the current cyanide monitoring requirements. The selected option adds standards for ammonia and the 23 organic pollutants determined to pass through (see 17), and modifies the monitoring point for the current cyanide pretreatment standards for Subcategories A and C.

EPA is setting pretreatment standards for ammonia for Subcategories A and C because of the high loads of ammonia currently being discharged by a number of pharmaceutical facilities to POTWs that do not have nitrification capability and receive wastewaters from Subcategory A and C facilities. However, EPA is aware that some POTWs treating pharmaceutical wastewaters from these subcategories have nitrification capability, and EPA has made a determination of no pass through for ammonia at these POTWs. Thus, PSES ammonia limitations will not apply to Subcategory A and C facilities discharging to POTWs with nitrification capability.

The pollutants regulated under the selected PSES option of Subcategories A and C have been determined to pass through and the pollutant removals are high with respect to the compliance costs. The costs for this option are economically achievable and the nonwater quality environmental impacts are acceptable.

For PSES for Subcategories B and D, EPA has selected the second option (organics only and withdraw cyanide). EPA is basing this selection on the fact that the five pollutants regulated under this option have been determined to pass through, and the pollutant removals are high with respect to the compliance costs. EPA has decided to withdraw the existing cyanide standards, since cyanide is not present in wastewaters for these subcategory facilities. The costs for this option are economically achievable, and the nonwater quality environmental impacts are acceptable.

11.6 PSNS

Pretreatment standards for new sources are designed to prevent the discharge of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of POTWs. The CWA requires pretreatment for pollutants that pass through POTWs or limit POTW sludge management alternatives, including the beneficial use of sludges on agricultural lands.

The development of regulatory options for PSNS is analogous to the development of options for NSPS, in that the new source has the opportunity to design and install the best and most efficient pharmaceutical manufacturing processes and wastewater treatment facilities. Accordingly, Congress directed EPA to consider the best demonstrated alternative processes, process changes, in-plant control measures, and end-of-pipe wastewater treatment technologies that reduce pollution to the maximum extent feasible. In response to that directive, EPA considered effluent reductions attainable by the most advanced and demonstrated process and treatment technologies at pharmaceutical manufacturing facilities. The factors considered in assessing PSNS include:

- The demonstration status of the process and wastewater treatment technologies;
- The cost of achieving effluent reductions;
- Nonwater quality environmental impacts; and
- Energy requirements.

EPA selected PSNS limits equal to PSES for Subcategories A, B, C, D. EPA was unable to identify a technology that would achieve greater removal of the pollutants to be controlled by the PSES being promulgated and is therefore promulgating PSNS equal to PSES for all four Subcategories.

Table 11-1

Summary of BPT, BAT, and PSES Regulatory Options

Regulation	Option Name	Technology Basis	
		Subcategory A and C Facilities	Subcategory B and D Facilities
BPT	No Revision (MACT Only)	Current Treatment Technology	Current Treatment Technology and Withdraw Cyanide
	Clarify Cyanide, Revise COD Only	Advanced Biological Treatment and Revised Monitoring Requirements for Cyanide	Advanced Biological Treatment and Withdraw Cyanide
	Clarify Cyanide, Revise BOD ₅ and TSS Only	Advanced Biological Treatment and Revised Monitoring Requirements for Cyanide	Advanced Biological Treatment and Withdraw Cyanide
	Clarify Cyanide and Revise BOD ₅ , TSS, & COD	Advanced Biological Treatment and Revised Monitoring Requirements for Cyanide	Advanced Biological Treatment and Withdraw Cyanide
BAT	Revise COD to BPT Limits and Clarify Cyanide	Advanced Biological Treatment and Revised Monitoring Requirements for Cyanide	Advanced Biological Treatment and Withdraw Cyanide
	Add Organics Only, Revise COD to BPT Limits, and Clarify Cyanide	Advanced Biological Treatment and Revised Monitoring Requirements for Cyanide	Advanced Biological Treatment and Withdraw Cyanide
	Add Organics and Ammonia, Revise COD to BPT Limits, and Clarify Cyanide	Advanced Biological Treatment with Nitrification, and Revised Monitoring Requirements for Cyanide	<i>Ammonia and cyanide limits do not apply for B/D facilities</i>
PSES	No Revision (MACT Only) and Clarify Cyanide	Current Treatment Technology and Revised Monitoring Requirements for Cyanide	Current Treatment Technology and Withdraw Cyanide
	Organics Only and Withdraw Cyanide	<i>This option was not considered for A/C Facilities</i>	In-Plant Steam Stripping for Organic Compounds and Withdraw Cyanide
	Organics and Ammonia, and Clarify Cyanide	In-Plant Steam Stripping for Organic Compounds and Ammonia, and Revised Monitoring Requirements for Cyanide (Nitrification may be used for Ammonia)	<i>Ammonia and Cyanide limits do not apply for B/D Facilities</i>
	Organics and Ammonia, and Revise Cyanide	In-Plant Steam Stripping for Organic Compounds and Ammonia, and In-Plant Cyanide Destruction (Nitrification may be used for Ammonia)	<i>Ammonia and Cyanide limits do not apply for B/D Facilities</i>